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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,459	11/28/2000	Gopinathan K. Menon	680.0041USU	6235

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EXAMINER	
OSTRUP, CLINTON T	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/723,459	MENON ET AL.	
	Examiner	Art Unit	
	Clinton Ostrup	1614	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2000*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 10-13 are pending in this application.

Response to Applicant's Arguments/Amendment

Withdrawn Claim Objections

Applicant's amendment filed September 25, 2003, Paper No. 20, to the objection of claims 13 has made the said objection moot. Moreover, the cancellation of claims 17 and 35 has made the objection to these claims moot. Therefore, the said objections have been withdrawn.

Withdrawn Claim Rejections

35 USC § 112, Second Paragraph

Applicant's cancellation of claim 16 in the amendment filed September 25, 2003, Paper No. 20, to the rejection of claim 16 under 35 U.S.C. 112, second paragraph, has made the said rejection moot. Therefore, the said rejection has been withdrawn.

MAINTAINED CLAIM REJECTIONS
35 USC § 102

Applicant's amendment and arguments filed September 25, 2003, Paper No. 20, to the rejection of claims 10-13 under 35 USC § 102(b) as being anticipated by MIKIMOTO PHARMACEUTICAL, CO, LTD., JP 07-126143 have been fully considered; however, Applicants arguments have not been found persuasive. Therefore, the said rejection has been MAINTAINED. The rejection of claims 15-21 and 31-38 has been withdrawn because of Applicants cancellation of said claims.

Applicants argue that although JP 07-126143 describe a cosmetic having an extract of *Lagerstroemia speciosa* for preventing skin roughness, skin glossiness, and

skin tension and that said composition is also used for whitening the skin, the reference lacks the method of treating the deterioration of collagen as claimed instantly.

First, a physician will typically examine many patients with various pathologies, and only some will have a particular disease requiring a particular treatment. It has been traditional in United States practice to recite the treatment of individuals "in need" of the treatment of a certain condition so as to indicate that particular subset of patients actually in need of intervention; an alternative is to recite the treatment of an individual "suffering from" a given disease. Accordingly, the following format is preferred for claiming methods of treating: "A method for treating disease X comprising administering to an individual suffering from/in need of such treatment an effective amount of agent Y". Claims not specifying the subset of patients to be treated in this manner are generally viewed as being anticipated by any prior art method using a given agent since they read on administration to the general population and not a specified subset requiring treatment.

Moreover, even if "in need thereof" language were to be adopted, the claims would still be anticipated insofar as it does not appear possible to isolate a subset of patients requiring the treatment of deteriorating collagen from the set of patients suffering from skin roughness, skin glossiness, and skin tension generally. Specifically, when the same composition is applied to the same substrate, it would have inherently treated the deterioration of collagen, as claimed. Stated alternatively, when the composition of JP-07-126143 was previously administered to treat patients suffering skin roughness, skin glossiness, and skin tension generally, it must have inherently

treated the deterioration of collagen, whether or not that fact was explicitly recognized. Thus, it does not appear possible to avoid treating patients suffering from skin roughness, skin glossiness, and skin tension generally with an extract of *Lagerstroemia speciosa,* from the corresponding claims in which the treatment of deterioration of collagen in skin is specified; because the actual treatment – administration of an extract of *Lagerstroemia speciosa* to the skin of a patient - is the same in both cases.

Applicant's arguments filed September 25, 2003, Paper No. 20, to the rejection of claims 10 and 13 under 35 USC § 102(b) as being anticipated by NIPPON KIKAKU KAIHATSU KK[[NIKJ], JP 05208913 A have been fully considered; however, Applicants arguments have not been found persuasive. Therefore, the said rejection has been MAINTAINED. The rejection of claims 15-19, 30-35, and 38 has also been withdrawn because of Applicants cancellation of said claims.

Applicants argue that although JP 05208913 A describe a composition comprising an extract of *Lagerstroemia speciosa,* the reference is teaching it to soften the stratum corneum, whereas instant claims 10-13 are *drawn to a* method of treating the deterioration of collagen.

First, a physician will typically examine many patients with various pathologies, and only some will have a particular disease requiring a particular treatment. It has been traditional in United States practice to recite the treatment of individuals "in need" of the treatment of a certain condition so as to indicate that particular subset of patients actually in need of intervention; an alternative is to recite the treatment of an individual "suffering from" a given disease. Accordingly, the following format is preferred for

claiming methods of treating: "A method for treating disease X comprising administering to an individual suffering from/in need of such treatment an effective amount of agent Y". Claims not specifying the subset of patients to be treated in this manner are generally viewed as being anticipated by any prior art method using a given agent since they read on administration to the general population and not a specified subset requiring treatment.

Moreover, even if "in need thereof" language were to be adopted, the claims would still be anticipated insofar as it does not appear possible to isolate a subset of patients requiring the treatment of deteriorating collagen from the set of patients suffering from skin roughness, skin glossiness, and skin tension generally. Specifically, when the same composition is applied to the same substrate, it would have inherently treated the deterioration of collagen, as claimed. Stated alternatively, when the composition of JP 05208913 A was previously administered to soften the stratum corneum of skin, thereby improving the aesthetic appearance of skin by promoting/accelerating cell turnover, improving skin tone, restoring skin luster, and minimizing signs of fatigue, it must have inherently treated the deterioration of collagen, whether or not that fact was explicitly recognized. Thus, it does not appear possible to avoid softening the stratum corneum of skin, thereby improving the aesthetic appearance of skin by promoting/accelerating cell turnover, improving skin tone, restoring skin luster, and minimizing signs of fatigue generally with an extract of *Lagerstroemia speciosa,* from the corresponding claims in which the treatment of deterioration of collagen in skin is specified; because the actual treatment -

administration of an extract of *Lagerstroemia speciosa* to the skin of a patient - is the same in both cases.

Applicant's arguments filed September 25, 2003, Paper No. 20, to the rejection of claims 10 and 13 under 35 USC § 102(b) as being anticipated by (MINI-N) MIKIMOTO SEIYAKU KK, JP 07157420 have been fully considered; however, Applicants arguments have not been found persuasive. Therefore, the said rejection has been MAINTAINED. The rejection of claims 15-18, 32-35, and 38 has also been withdrawn because of Applicants cancellation of said claims.

Applicants argue that although JP 07157420 describe a cosmetic material having skin whitening, anti-oxidation and hyaluronidase inhibition activities as well as good skin moisturizing effects, the reference lacks the method of treating the deterioration of collagen as claimed instantly.

First, a physician will typically examine many patients with various pathologies, and only some will have a particular disease requiring a particular treatment. It has been traditional in United States practice to recite the treatment of individuals "in need" of the treatment of a certain condition so as to indicate that particular subset of patients actually in need of intervention; an alternative is to recite the treatment of an individual "suffering from" a given disease. Accordingly, the following format is preferred for claiming methods of treating: "A method for treating disease X comprising administering to an individual suffering from/in need of such treatment an effective amount of agent Y". Claims not specifying the subset of patients to be treated in this manner are generally viewed as being anticipated by any prior art method using a given agent since

they read on administration to the general population and not a specified subset requiring treatment.

Moreover, even if "in need thereof" language were to be adopted, the claims would still be anticipated insofar as it does not appear possible to isolate a subset of patients requiring the treatment of deteriorating collagen from the set of patients in need of skin whitening, anti-oxidation and hyaluronidase inhibition activities to good skin moisturizing effects generally. Specifically, when the same composition is applied to the same substrate, it would have inherently treated the deterioration of collagen, as claimed. Stated alternatively, when the composition of JP 07157420 was previously administered to whiten skin, provide anti-oxidation and hyaluronidase inhibition activities and to give good skin moisturizing effects generally, it must have inherently treated the deterioration of collagen, whether or not that fact was explicitly recognized. Thus, it does not appear possible to avoid whitening skin, providing anti-oxidation and hyaluronidase inhibition activities and to give good skin moisturizing effects generally with an extract of *Lagerstroemia speciosa,* from the corresponding claims in which the treatment of deterioration of collagen in skin is specified; the actual treatment – administration of an extract of *Lagerstroemia speciosa* to the skin of a patient - is the same in both cases.

New objections

The amendment filed September 25, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no

amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows:

Claims 10-13 have been amended to a method of treating deterioration of collagen in skin, comprising topically applying to the skin: a composition having an effective amount of crape myrtle extract to treat the deterioration of collagen; and a cosmetically acceptable vehicle. However, the specification lacks support for a method of treating deterioration of collagen in skin. Applicant states on Page 5, lines 12-16, of the Amendment filed September 25, 2003, Paper No. 20, that Example 2 supports the premise of prevention of the deterioration of collagen because the data show an increase in fibroblast production activity and increase in fibroblast activity directly translates into an increase in collagen production.

Applicant has not provided any evidence to demonstrate that an increase in fibroblast production activity and increase in fibroblast activity directly translates into an increase in collagen production and the specification does not provide such evidence. Therefore, it is the examiner's position that the method of treatment as claimed has not been described in sufficient detail to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is required to cancel the new matter in the reply to this Office Action.

NEW CLAIM REJECTIONS

New Matter Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10-13 are directed to a method of treating deterioration of collagen in skin, comprising topically applying to the skin: a composition having an effective amount of crape myrtle extract to treat the deterioration of collagen; and a cosmetically acceptable vehicle. However, the specification lacks support for a method of treating deterioration of collagen in skin. Applicant states on Page 5, lines 12-16, of the Amendment filed September 25, 2003, Paper No. 20, that Example 2 supports the premise of prevention of the deterioration of collagen because the data show an increase in fibroblast production activity and increase in fibroblast activity directly translates into an increase in collagen production.

Applicant has not provided any evidence to demonstrate that an increase in fibroblast production activity and increase in fibroblast activity directly translates into an increase in collagen production and the specification does not provide such evidence. Therefore, it is the examiner's position that the method of treatment as claimed has not

been described in sufficient detail to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614